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Nucletron

NUCLETRON B.V.
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Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Regulatory Affairs Manager

Modified Device Name:

Trade/Proprietary Name:	Implant Guidance System Applicator Set
Common/Usual Name:	Remote Afterloading for interstitial brachytherapy applications
Classification Name:	Remote controlled radionucide applicator system accessory
Classification	21 CFR 892.5840, Class II

Legally Marketed Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron B.V.	Speiser Needle Set	K953946
Nucletron B.V.	Flexible Implant Tubes	K953946
Nucletron B.V.	Interstitial Needle Set	K953946

Description:

The Nucletron Implant Guidance System as described in this submission is designed as an accessory to the Nucletron remote afterloading equipment, mHDR, and is intended for interstitial brachytherapy procedures.

The Nucletron Implant Guidance System Applicator Set consists of an insertion needle with a plastic sheath, which is inserted through the skin surface into the target

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volume. The insertion needle is then removed and a closed end plastic catheter is placed into the sheath. A marker on the side of the insertion obturator insures the proper depth of catheter placement. Once the catheter is in place the sheath is removed and a button is placed over the plastic catheter and slid into contact with the skin surface. The catheter is then cut level with the button and attached. A closed end treatment needle is then inserted into the catheter, once in position a metal needle stopper is slid over the needle to the button surface and locked. Radiographic images, planar films or transverse slices, i.e. CT, MR is obtained to determine the precise location of the applicator within the body. This information is then used for brachytherapy treatment planning purposes. When the treatment planning is completed the treatment needle is then attached to the Nucletron remote afterloading equipment (treatment head), mHDR, by the Nucletron transfer tubes. The transfer tubes lock onto the open end of the treatment needles and the remote afterloading equipment (treatment head) prior to treatment. When the applicator is attached, a check cable run is performed to ensure that the applicator is properly attached and that there are no obstructions, which will interrupt treatment. After the check cable run, the radioactive source will step through the applicator to deliver the prescribed dose of radiation. When the treatment session is complete, the treatment needles are detached from the transfer tube and remote afterloading equipment. The treatment needles are then removed from the patient. When the course of treatment is completed the catheters and buttons are removed from the patient.

The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids. The applicator does not control the treatment unit; it strictly provides a treatment path for the radioactive source. The Nucletron remote afterloading system and the clinical staff verify that the applicator is properly attached prior to treatment.

Intended use:
Nucletron Implant Guidance System Applicator Set is intended for interstitial brachytherapy procedures involving the Nucletron remote afterloading equipment: mHDR. The applicator provides a means of delivering the prescribed radiation dose to the treatment area. The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids.

Summary of technological considerations:
The Nucletron Implant Guidance System Applicator Set is substantially equivalent to the cleared predicate devices, Speiser Needle Set (#K953946), Flexible Implant Tubes (#K953946) and Interstitial Needle Set (#K953946).

Ulrich G. Fz — 11.02.02

Name: U. Lutz
Title: Business Segment Manager
HDR Brachytherapy
Nucletron B.V.
Veenendaal, The Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2002

Ms. Lisa C. Dimmick
Regulatory Affairs Manager
Nucletron Corporation
7080 Columbia Gateway Drive
COLUMBIA MD 21046-2133

Re: K020015
Trade/Device Name: Implant Guidance System Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: February 11, 2002
Received: February 19, 2002

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Nucletron

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Statement of intended use

Device Name: Implant Guidance System Applicator Set

Intended Use:
Nucletron Implant Guidance System Applicator Set is intended for interstitial brachytherapy procedures involving the Nucletron remote afterloading equipment: mHDR. The applicator provides a means of delivering the prescribed radiation dose to the treatment area. The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids.

Prescription use:
The Nucletron Implant Guidance System Applicator Set is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

Ulrike-B. Lz — 10.12.01

Name: U. Lutz
Title: Business Segment Manager
HDR Brachytherapy
Nucletron B.V.
Veenendaal, The Netherlands

Date

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020015